

PCT/SE 2004 / 0 0 0 5 5 8

07-04-2004

REC'D 23 APR 2004

WIPO

PCT

PA 1144858

THE UNITED STATES OF AMERICA

TO ALL TO WHOM THESE PRESENTS SHALL COME:

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

March 16, 2004

THIS IS TO CERTIFY THAT ANNEXED HERETO IS A TRUE COPY FROM THE RECORDS OF THE UNITED STATES PATENT AND TRADEMARK OFFICE OF THOSE PAPERS OF THE BELOW IDENTIFIED PATENT APPLICATION THAT MET THE REQUIREMENTS TO BE GRANTED A FILING DATE UNDER 35 USC 111.

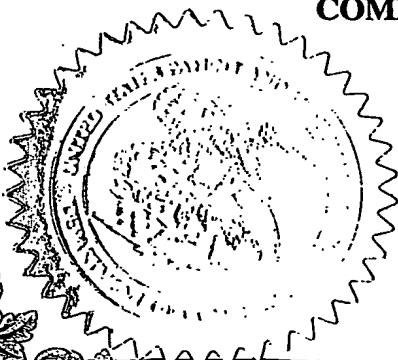
APPLICATION NUMBER: 60/461,658

FILING DATE: April 07, 2003

PRIORITY DOCUMENT

SUBMITTED OR TRANSMITTED IN
COMPLIANCE WITH RULE 17.1(a) OR (b)

**By Authority of the
COMMISSIONER OF PATENTS AND TRADEMARKS**



T. Wallace
T. WALLACE
Certifying Officer

BEST AVAILABLE COPY



04-10-03

60461658 . 04/07/03

TRANSMITTAL FORM



Electronic Version 1.0.3

Stylesheet Version: 1.0

Submission Type: Provisional
Application

Attorney Docket
Number:

N026
US

A Device for Use in A Cartridge, and A Cartridge

First Named Inventor: Jan Olof LORENTZON

SUBMITTED BY

Name:

Peter B. Scull

Registration Number:

37932

Electronic Signature Mark:

Date Signed:

April 7, 2003

I certify that the use of this system is for OFFICIAL correspondence between patent applicants or their representative and the USPTO. Fraudulent or other use besides the filing of official correspondence by authorized parties is strictly prohibited, and subject to a fine and/or imprisonment under applicable law.

I, the undersigned, certify that I have viewed a display of document(s) being electronically submitted to the United States Patent and Trademark Office, using either the USPTO provided style sheet or software, and that this is the document(s) I intend for initiation or further prosecution of a patent application noted in the submission. This document(s) will become part of the official electronic record at the USPTO.

Attached Files:

bibd-transmittal

N0267US01apds.xml

fee-transmittal

N0267US01fee.xml

Certificate of Express Mailing
Application Data Sheet
Specification (27 pages)
Drawings (8 sheets)
Return Card

file://C:\Program%20Files\USPTO\efiling\N0267US01\tranN0267US01.xml

4/7/03

Comments:

FEE TRANSMITTAL

JC962 U.S. PTO
04/07/03

Electronic Version 1.1.2

Stylesheet Version: 1.0

Patent fees are subject to annual revisions on or about October 1st of each year.

Large Entity

TOTAL FEES AUTHORIZED: \$ 160The commissioner is hereby authorized to charge indicated processing and/or publication fees :
credit any overpayments to:

Deposit Account Number:

03-2316 yh 04/07/2003
~~93-2316~~03-2316 yh 04/07/2003
93-2316

Deposit Account Name:

Gambro, Inc.

Charge Any Additional Fee Required Under 37 C.F.R. Sections 1.16 and 1.17.

Charge Assignment Fees Required Under 37 C.F.R. Section 1.21 (h).

SUBMITTED BY

Authorized Name:

Peter B. Scull

Electronic Signature Mark:

Date Signed:

Pete B Scull

BASIC FILING FEE

April 7, 2003

Fee Description	Fee Code	Fee Paid
Provisional Filing Fee	1005	\$

Subtotal For Basic Filing Fee: \$

Docket No. N0267-US01

IN THE UNITED STATES
PATENT AND TRADEMARK OFFICE

In re Application of: LORENZON, et al. }

Serial No.: To be assigned }

Filed: Herewith }

For: A Device for Use in A Cartridge, and
A Cartridge }

Customer Number: 24994 }

Group Art No: To be assigned

Examiner: To be assigned

CERTIFICATE OF MAILING BY "EXPRESS MAIL" (37 CFR 1.10)

I hereby certify that the following documents:

1. This Certificate of Express Mailing (1pg)
2. Provisional Transmittal Form (2pgs)
3. Fee Transmittal and a duplicate (2pgs)
4. Application Data Sheet (2pgs)
5. Specification (27pgs)
6. Drawings (8 sheets)
7. Return Card

are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 in an envelope addressed to:

Box Provisional - Patent Application
Commissioner for Patents
P.O. BOX 1450
Alexandria, VA 22313-1450

on this date of 04/07/2003


Yanmin Huang

EV 116731822 US

Express Mailing Label Number

APPLICATION DATA SHEET

Electronic Version 0.0.11

Stylesheet Version: 1.0

Attorney Docket Number: N0267-US

Publication Filing Type:

new-utility

Application Type:

utility

Title of Invention:

A Device for Use in A Cartridge, and A Cartridge

Customer Number Attorney:

24994

24994

Customer Number Correspondence Address:

24994

24994

INVENTOR(s):

Primary Citizenship: Sweden
Given Name: Jan Olof
Family Name: LORENTZON
Residence City: Lund
Residence Country: SE
Address: Cymbalvagen 20
Lund , SE-24500 SE

Primary Citizenship: Sweden
Given Name: Ingvar
Middle Name: Ernst
Family Name: LOSELL
Residence City: Staffanstorp
Residence Country: SE
Address: Cymbalvagen 20
Staffanstorp , SE-24500 SE

Primary Citizenship: Sweden
Given Name: Ragnar

Family Name: TRYGGVASON
Residence City: Loddekopinge
Residence Country: SE
Address: Dosvagen 13
Loddekopinge , SE-24021 SE

5

A Device for Use in A Cartridge, and A Cartridge**BACKGROUND OF THE INVENTION AND PRIOR ART**

- 10 The present invention generally relates to a preparation of a liquid solution intended for a medical procedure, in particular to on-line preparation of a sodium chloride or sodium bicarbonate solution for hemodialysis. The on-line preparation in view takes place in a cartridge containing a particulate or granular material, such as
- 15 sodium bicarbonate or sodium chloride.

More specifically, the invention relates to a device for use in a cartridge for preparing a liquid solution for a medical procedure.

- 20 Further, the present invention relates to a cartridge for preparing a liquid solution for a medical procedure and arranged to contain a particulate material, wherein the cartridge includes: an inner space for housing the particulate material; an inlet arranged to permit the introduction of a liquid into the inner space; and an outlet arranged
- 25 to permit the discharge of liquid from the inner space.

- Still further, the present invention relates to a use of a device in a cartridge for preparing a liquid solution for a medical procedure and arranged to contain a particulate material, wherein the cartridge
- 30 includes: an inner space for housing the particulate material; an inlet arranged to permit the introduction of a liquid into the inner space; and an outlet arranged to permit the discharge of liquid from the inner space.

- 35 The present invention also refers to a system for preparing a liquid solution for a medical procedure, the system including: a cartridge containing a particulate material in an inner space thereof and

including an inlet and an outlet; a first liquid conduit having a first end communicating with a source of liquid to withdraw the liquid into the first liquid conduit and a second end for delivering said liquid solution; a second liquid conduit having a first end communicating with a source of liquid and a second end communicating with the inlet of the cartridge for introducing the liquid into the inner space to produce a concentrate liquid solution containing at least a part of the particulate material dissolved in the liquid; a third liquid conduit communicating with the outlet and with a mixing point in the first liquid conduit intermediate said first and second ends for conducting said concentrate liquid solution from the cartridge into said first liquid conduit to be mixed with the liquid being conducted through the first liquid conduit to thereby produce said liquid solution in the first liquid conduit for delivery to said second end of the first liquid conduit.

Dialysis is a well-known method for treatment of kidney insufficiency. In hemodialysis, the blood of a patient suffering from impaired kidney function is conducted from a patient blood vessel to a dialysis machine and is returned to the patient after the treatment. The blood is conducted along one side of a permeable membrane in a dialyser or filter connected to the dialysis machine, at the same time as dialysis liquid or dialysate may be conducted along the opposite side of the same membrane. Waste substances or poisons are removed from the blood by means of diffusion and/or convection from the blood to the dialysis liquid through the membrane. Excess water is also removed from the blood.

On-line preparation of dialysis liquid is known. For example, on line preparation of a saturated bicarbonate solution from particulate bicarbonate contained in a cartridge is disclosed in DE-A-19801107.

Also EP-B-278100 discloses such a cartridge. The cartridge comprises a closed vessel provided with penetrateable membranes at its upper inlet end and its lower outlet end, respectively. Within the vessel, there is provided a bed of particulate material of sufficient quantity so as to be suitable for one dialysis treatment

session. For instance, in connection with the preparation of a dialysis liquid, the concentrate may consist of particulate sodium chloride or sodium bicarbonate. The quantity thereof contained in the cartridge may be of the order of magnitude of 400-1500 grams.

5

In use, such a cartridge is first primed with a liquid, such as water, either from the top or from the bottom. Enough liquid is introduced into the cartridge during priming so that the liquid level is above the level of the particulate material. The particulate material is dissolved in the liquid and a saturated solution can leave the cartridge through the outlet in the bottom of the cartridge. As the solution leaves the cartridge a corresponding amount of new liquid is introduced into the cartridge. To establish that the degree of saturation of the solution leaving the cartridge is satisfactory, the conductivity of the solution may be measured. If an unsatisfactory saturation is detected by sensing the conductivity of the solution, an alarm in the dialysis machine may be triggered.

The above mentioned way of on-line preparation of liquid solutions for medical use by means of a cartridge containing particulate material has many advantages. There are, however, some disadvantages with the prior art cartridges. After a few hours of use, the mixture of the liquid and the particulate material in the cartridge may become inhomogenous. In some instances, clods may be formed. Moreover, in use of the cartridge, gas bubbles containing carbon dioxide may be formed. The clods may prevent such gas bubbles from rising to the liquid surface. When a bubble then is released, a channel may be created in the particulate material, which some times may extend all the way down to the lower outlet of the cartridge. This may allow unsaturated solution to leave the cartridge causing a conductivity alarm. The alarm must be taken care of either by the patient or by a nurse or medical attendant. If these problems occur, they may be remedied by knocking on the cartridge wall or by shaking the cartridge. However, the cartridge often has to be discarded, while still containing a considerable amount of particulate material, and replaced by a new cartridge. The changing of a cartridge is time-consuming and costly.

The formation of channels in the particulate material might have other causes. For example, the liquid may be introduced gradually through the top inlet and fall in drops down to and impact the liquid surface. This may give rise to pressure waves in the liquid, which in turn create liquid currents perpendicular to the surface of the bed of particulate material. These currents may work their way down in the bed of particulate material, creating channels in the particulate material reaching the lower outlet making it possible for unsaturated solution to leave the cartridge.

Another problem with the cartridges used up to now is the risk that the particulate material can escape via the inlet and the outlet. In order to reduce this risk, a felt pad or any similar porous member is incorporated in the inlet and the outlet. In particular, during the priming of the cartridge from below, i.e. via the outlet, the porous felt pad at the inlet is important. The porous felt pad is normally manufactured in another material than the rest of the cartridge, which is disadvantageous from a recycling point of view.

A further problem in connection with such cartridge is the potential risk of leakage of the particulate material before the cartridge is taken into use. Today this problem has been solved by arranging a closing mechanism over the inlet and outlet of the cartridge. Before use and connection to the dialysis machine of the cartridge, the closing mechanism has to be open. The closing mechanism may be, for instance, in the form of a valve, a removable cap or a solid cover to be broken by means of a sharp tool.

SUMMARY OF THE INVENTION

The object of the present invention is to enable an improvement of the preparation of a liquid solution for a medical procedure, in particular a sodium chloride or bicarbonate solution for dialysis treatment, such as hemodialysis HD, hemofiltration HF or hemodiafiltration HDF among others. More specifically, the object is to provide a proper distribution of a liquid in a cartridge containing a

Atty. Docket No. N0267-US01

particulate material. A further object is to prevent the particulate material from leaving the cartridge in an undesired manner.

5 This object is achieved by a device for use in a cartridge for preparing a liquid solution for a medical procedure, said device comprising a hollow body defined by a wall enclosing a cavity space of the body, the body having a first end and a second end, and being provided with a least one slit-shaped opening extending through the wall, said first end being open and adapted for
10 receiving liquid to be introduced into the cartridge, which liquid leaves the device through said slit-shaped opening in a flow direction, wherein said slit-shaped opening has a first extension and a second extension being substantially perpendicular to the flow direction and to the first extension, wherein the second extension is
15 significantly shorter than the first extension.

By means of such a device in a cartridge with particulate material, the liquid continuously introduced in the cartridge may be distributed in a desired way so as to minimise the risk of formation
20 of channels and inhomogeneities in the particulate material. In turn this minimises the risk of unsaturated solution leaving the cartridge. The chance that the whole amount of particulate material in the cartridge can be used is thus increased. Moreover, during the initial priming of the cartridge, the device provides a more even
25 distribution of the liquid. Due to the thin slit-shaped openings a desired pressure drop over the wall of the hollow body may be achieved. The desired pressure drop may be chosen so as to reduce the risks for channelling.

30 Furthermore, thanks to the thin slit-shaped openings any particles of the particulate material having a minimum size larger than the second extension will be efficiently prevented from leaving the cartridge via the inlet, especially before the device is used. This permits a simple and inexpensive handling of the cartridge before
35 the actual use, for instance by means of the provision of an easily removable cap for closing the inlet before the device is to be used. Moreover, the previously used felt pad may be dispensed with.

Atty. Docket No. N0267-US01

According to an embodiment of the present invention, said hollow body has a centre axis and an elongated, tubular shape along the centre axis. By means of such an elongated shape, it is possible to
5 let the liquid be output below the liquid/air surface also when the liquid level is sinking gradually. Therefore, the liquid will not fall in drops down onto the liquid surface. The generation of pressure waves is thus avoided. Consequently, the formation of channels in the particulate material is minimised.

10 According to a further embodiment of the present invention, said hollow body is tapering along the centre axis towards the second end. By means of such tapering shape, the device can easily be stuck into the dry particulate material when the cartridge is
15 prepared.

According to a further embodiment of the present invention, said hollow body at the first end has engaging means adapted for connection of the device to the cartridge.

20 According to a further embodiment of the present invention, the second extension is significantly shorter than the length of the slit-shaped opening in the flow direction. This feature permits a certain wall thickness of the body of the device ensuring a sufficient
25 strength of the device. Preferably, the first extension is substantially perpendicular to the flow direction.

According to a further embodiment of the present invention, the second extension is equal to or less than 0,1 mm, preferably equal
30 to or less than 0,08 mm. Moreover, the second extension may be equal to or more than 0,02 mm, preferably equal to or more than 0,04 mm. According to an advantageous embodiment, the second extension is approximately 0,06 mm.

35 According to a further embodiment of the present invention, the device includes a plurality of slit-shaped openings, which extend through the wall. The total flow area of the slit-shaped openings

Atty. Docket No. N0267-US01

governing the speed of the supply of liquid may in a convenient manner be adjusted by the selection of an appropriate number of slit-shaped openings.

5 According to a further embodiment of the present invention, said slit-shaped openings are distributed around the wall. In such way, the liquid supply into the particulate material may be uniformly distributed. It is to be noted that the hollow body may have any cross-sectional shape, such as a circular, oval, triangular, square,
10 rectangular or any other polygonal shape. In case of a rectangular or square cross-sectional shape, an appropriate liquid distribution may be obtained even if slit-shaped openings are arranged through only one or two of the side walls of such a shape.

15 According to a further embodiment of the present invention, said hollow body has a wall portion at least in the proximity of the second end, and wherein said slit-shaped opening extend through said wall portion. Such a wall portion at the second lower end permits the slit-shaped opening or openings at least initially to be
20 located beneath the upper liquid surface. However, such a wall portion is useful even if the liquid surface is located below the wall portion.

25 According to a further embodiment of the present invention, said wall portion has a tip-like shape, especially said wall portion may be substantially conical.

30 According to further embodiment of the present invention, said wall portion is substantially plane. Such a substantially plane wall portion is advantageous from a manufacturing point of view, since it permits a relatively simple injection moulding process. According to one alternative, a normal direction of said wall portion may form an angle of inclination to the centre axis, wherein the flow direction forms an angle to the centre axis. According to another alternative,
35 the centre axis extends substantially in parallel with a normal direction of the plane.

Atty. Docket No. N0267-US01

- According to a further embodiment of the present invention, the slit-shaped opening has an upstream end and a downstream end with respect to the flow direction, wherein the second extension of the slit-shaped opening increases in the flow direction from a minimum value at the upstream end of the slit-shaped opening to a maximum value at the downstream end of the opening. Such a shape of the slit-shape opening or openings is also advantageous from a manufacturing point of view.
- 10 The object is also achieved by a cartridge for preparing a liquid solution for a medical procedure and arranged to contain a particulate material, wherein the cartridge includes: an inner space for housing the particulate material; an inlet arranged to permit the introduction of a liquid into the inner space; an outlet arranged to permit the discharge of liquid from the inner space; and a device comprising a hollow body defined by a wall enclosing a cavity of the body, the body having a first end and a second end, and being provided with a least one slit-shaped opening extending through the wall, said first end being mounted to the cartridge at the inlet in such a manner that the body extends into the inner space and said second end is located in the inner space of the cartridge, said first end being open and adapted for receiving said liquid to be introduced into the cartridge, which liquid leaves the device through said slit-shaped opening in a flow direction, wherein said slit-shaped opening has a first extension and a second extension being substantially perpendicular to the flow direction and to the first extension, wherein the second extension is significantly shorter than the first extension. Advantageous embodiments of the cartridge are defined in the dependent claims 24 and 25.
- 30 According to an advantageous embodiment, the cartridge may thus be provided with a device provided at the inlet and having at least one thin slit-shaped opening, and a filter provided at the outlet and having at least one slit-shaped opening. By such a cartridge, the particulate material in the solid state may be securely maintained in the cartridge.
- 35

Atty. Docket No. N0267-US01

The object is also achieved by a use of a device in a cartridge for preparing a liquid solution for a medical procedure and arranged to contain a particulate material, wherein the cartridge includes: an inner space for housing the particulate material; an inlet arranged to
5 permit the introduction of a liquid into the inner space; an outlet arranged to permit the discharge of liquid from the inner space; and said device comprising a hollow body defined by a wall enclosing a cavity of the body, the body having a first end and a second end, and being provided with a least one slit-shaped opening extending
10 through the wall, said first end being mounted to the cartridge at the inlet in such a manner that the body extends into the inner space and said second end is located in the inner space of the cartridge, said first end being open and adapted for receiving said liquid to be introduced into the cartridge, which liquid leaves the device through
15 said slit-shaped opening in a flow direction, wherein said slit-shaped opening has a first extension and a second extension being substantially perpendicular to the flow direction and to the first extension, wherein the second extension is significantly shorter than the first extension, the use including the step of supplying said
20 liquid to the cartridge via the inlet in such a way that the liquid passes through the particulate material and thereby dissolves at least a part of the particulate material to form a liquid solution. Advantageous embodiments of the use are defined in the dependent claims 27 to 30.

25 The object is also achieved by a system for preparing a liquid solution for a medical procedure, the system including: a cartridge containing a particulate material in an inner space thereof and including an inlet and an outlet; a first liquid conduit having a first
30 end communicating with a source of liquid to withdraw the liquid into the first liquid conduit and a second end; a second liquid conduit having a first end communicating with a source of liquid and a second end communicating with the inlet of the cartridge for introducing the liquid into the inner space to produce a concentrate
35 liquid solution containing at least a part of the particulate material dissolved in the liquid; a third liquid conduit communicating with the outlet of the cartridge and with a mixing point in the first liquid

Atty. Docket No. N0267-US01

conduit intermediate said first and second ends for conducting said concentrate liquid solution from the cartridge into said first liquid conduit to be mixed with the liquid being conducted through the first liquid conduit to thereby produce said liquid solution in the first liquid conduit for delivery to said second end of the first liquid conduit; and a device comprising a hollow body defined by a wall enclosing a cavity of the body, the body having a first end and a second end, and being provided with a least one slit-shaped opening extending through the wall, said first end being mounted to the cartridge at the inlet in such a manner that the body extends into the inner space and said second end is located in the inner space of the cartridge, said first end being open and adapted for receiving said liquid to be introduced into the cartridge, which liquid leaves the device through said slit-shaped opening in a flow direction, wherein said slit-shaped opening has a first extension and a second extension being substantially perpendicular to the flow direction and to the first extension, wherein the second extension is significantly shorter than the first extension. Advantageous embodiments of the system are defined in the dependent claims 32 to 36.

BRIEF DESCRIPTION OF THE DRAWINGS

The present invention is now to be described more closely by the following description of various embodiments and with reference to the drawings attached.

- Fig 1 discloses schematically a system for preparing a liquid solution for a medical procedure.
- Fig 2 discloses schematically a cartridge including a device according the present invention.
- Fig 3 discloses schematically a plan view of a filter to be arranged in the cartridge of Fig 2.
- Fig 4 discloses schematically a sectional view of the filter along the line IV-IV in Fig 3.
- Fig 5 discloses schematically a sectional view of the filter along the line V-V in Fig 3.

Atty. Docket No. N0267-US01

- Fig 6 discloses schematically a longitudinal sectional view of a part of the device arranged in the cartridge of Fig 2.
- Fig 7 discloses schematically a transversal sectional view of the part of the device arranged in the cartridge of Fig 2.
- 5 Fig 8 discloses schematically a perspective view a first embodiment of the device arranged in the cartridge of Fig 2.
- Fig 9 discloses schematically a perspective view a second embodiment of a device to be arranged in the cartridge of Fig 2.
- 10 Fig 10 discloses schematically a perspective view a third embodiment of a device to be arranged in the cartridge of Fig 2.
- Fig 11 discloses schematically a perspective view a fourth embodiment of a device to be arranged in the cartridge of Fig 2.
- 15

DETAILED DESCRIPTION OF VARIOUS EMBODIMENTS OF THE INVENTION

20

Fig 1 discloses schematically a system for preparing a liquid solution for a medical procedure. In particular, the system is designed for preparing a dialysis liquid solution for the performance of a hemodialysis treatment. The system may also be used for hemodiafiltration and hemofiltration. The system disclosed in Fig 1 may thus form a part of a dialysis equipment.

25

The system includes a source 1 containing a liquid, and in particular a dialysis liquid. The source 1 may be supplied with the liquid via an inlet conduit 2. A first liquid conduit 3 has a first end 4 communicating with the source 1 to withdraw the dialysis liquid into the first liquid conduit 3. The first liquid conduit 3 also has a second end 5 for delivering a dialysis liquid solution to a receiver (not disclosed) such as a dialysis equipment. A second liquid conduit 6 has a first end 7 communicating with the source 1 and a second end 8 communicating with the inlet of a cartridge 9 for the introduction of the liquid from the source 1 into an inner space 10 of the

30

35

Atty. Docket No. N0267-US01

cartridge 9 to produce a concentrate liquid solution. A third liquid conduit 11 has a first end 12 communicating with the outlet of the cartridge 9 and a second end 12 communicating with the first liquid conduit 3 at a mixing point 13 intermediate said first end 4 and said
5 second end 5.

The third liquid conduit 11 is thus arranged to withdraw said concentrate liquid solution from the cartridge 9 into the first liquid conduit 3 to be mixed with the liquid conducted through the first
10 liquid conduit 3 from the source 1 in order to produce a liquid solution for delivery to said receiver. The concentrate liquid solution is transported through the third liquid conduit 11 by means of a pump 15. The liquid is transported from the source 1 to said receiver through the first liquid conduit 3 by means of a pump 16. A
15 control loop 17 including a valve 18 may be arranged to control the quantity of concentrate liquid solution to be delivered to the liquid of the first liquid conduit 3.

The cartridge 9 is explained below with reference to Fig 2. In the
20 embodiment disclosed, it is referred to the production of a dialysis liquid solution to which sodium bicarbonate has been added. It is to be noted that also other substances than sodium bicarbonate can be added in a similar manner to the dialysis liquid, for instance sodium chloride and other salts. It is also to be noted, that the
25 system, the cartridge and the components included therein can be used also for producing other liquid solutions than a dialysis liquid.

The cartridge 9 is arranged to contain a particulate material 20 in the inner space 10. In the embodiment disclosed the particulate
30 material 20 is a sodium bicarbonate powder. The cartridge 9 has an inlet 21 which is arranged to permit the introduction of a liquid into the inner space 10. In the embodiment disclosed, the inlet 21 is connected to and communicates with the second liquid conduit 6. The cartridge 9 also has an outlet 22 arranged to permit the
35 discharge of liquid from the inner space 10. In the embodiment disclosed, the outlet 22 is connected to and communicates with the third liquid conduit 11 for discharging the concentrate liquid

Atty. Docket No. N0267-US01

5 solution. The cartridge disclosed in Fig 2 has been prepared for use. In a first step, air has been sucked from the cartridge 9 for the purpose of creating a vacuum in the cartridge 9. Then the cartridge 9 has been primed with a liquid 28, i.e. a solvent, such as water, by letting the liquid 28 flow into the cartridge 9. As appears from Fig 2, the liquid 28 forms a liquid layer, wherein the level of the liquid 28 is above the level of the particulate material 20.

10 A filter 23 is arranged at the outlet 22 to permit passage of said liquid through the filter 23, but to prevent the passage of the particulate material 20 through the filter 23. The filter 23 defines a filter direction a, see Figs 4 and 5, and thus permits the liquid to pass through the filter 23 in the filter direction a. The cartridge 9 also includes a device in the form of an elongated hollow body 24
15 arranged at the inlet 21 to permit passage of the liquid through the hollow body 24, but to prevent passage of the particulate material 20 through the hollow body 24. The hollow body 24 has a centre axis x, extending substantially vertically during normal use of the device and the cartridge 9. The centre axis x also forms a centre axis x for
20 the cartridge 9. The hollow body 24 defines a flow direction b, see Figs 6 and 7, and permits the liquid to pass through the hollow body 24 in the flow direction b into the inner space 10.

25 The filter 23 rests on a support member in the form of a shoulder 25 extending around the inner periphery of the inner space 10 in the proximity of the outlet 22. A smaller shoulder 26 extends around the inner periphery of the inner space 10 above the filter 23 in order to permit the locking of the filter 23 at its position on the shoulder 25. Two different embodiments of the filter 23 are explained below with
30 reference to Figs 3-7.

35 Figs 3-5 disclose an embodiment of the filter 23. The filter 23 has the shape of a substantially circular and substantially plane disc 29 having a main extension plane. It is to be noted, that the thickness of the disc 29 is exaggerated in the figures in order to simplify the explanation of the filter construction. The filter 23 includes a number of slit-shaped openings 30. Each such opening 30 has a

Atty. Docket No. N0267-US01

first extension, indicated by the line 31 in Fig 3 for one of the openings 30. Each opening 30 also has a second extension, indicated by the line 32 in Figs 3 and 5. The second extension 32 is substantially perpendicular to the first extension 31. Both the
5 second extension 32 and the first extension 31 are substantially perpendicular to the filter direction a.

The second extension 32 is significantly shorter than the first extension 31. Moreover, the second extension 32 is also
10 significantly shorter than the length 33 of the slit-shaped opening 30 in the filter direction a. For instance the length 33 may be 10 – 1000 times the second extension 32. In particular, the second extension 32 is equal to or less than 0,1 mm, preferably equal to or less than 0,08 mm. Moreover, the second extension 32 is equal to or more
15 than 0,02 mm, preferably equal to or more than 0,04 mm. According to a preferred embodiment, the second extension 32 is approximately 0,06 mm.

The slit-shaped openings 30, which extend through the disc 29, are,
20 in the embodiment disclosed, provided to extend in a radial direction with regard to the first extension 31 and a centre point of the disc 29. However, the slit-shaped openings 30 may also be arranged to extend in other directions, for instance the disc 29 may include a plurality of slit-shaped openings 30 extending in parallel to
25 each other. The disc 29 is made in a polymer material, for instance polycarbonate or polypropylene. The disc 29 may be manufactured through an injection moulding process by injecting said polymer material into a mould cavity having the shape of the disc 29. Each slit-shaped opening 30 has an upstream end and a downstream end
30 with respect to the filter direction a. As appears from Fig 5, the second extension 32 of the slit-shaped opening 32 increases in the filter direction a from a minimum value at the upstream end of the slit-shaped opening 30 to a maximum value at the downstream end of the slit-shaped opening 30. Such a shape of the slit-shaped
35 opening facilitates the injection moulding of the disc 29.

Atty. Docket No. N0267-US01

5 The filter 23 includes a circumferential flexible edge portion 36 formed as a part of the disc 29. The edge portion 36 is flexible in an radial inward direction and formed by the provision of a circumferential groove 37 extending radially inside the edge portion 36. Consequently, the flexible edge portion 36 may be bent radially inwardly when the filter 23 is introduced at its position on the shoulder 25 in order to pass the shoulder 26. After having passed the shoulder 26, the flexible edge portion 36 may flex back to the outer position disclosed in Fig 4.

10 The device in the form of the hollow body 24, and its arrangement in the cartridge 9, is now to be explained more closely with reference to Figs 2 and 6 to 11, disclosing different embodiments of the hollow body 24. The hollow body 24 has an elongated extension
15 along the centre axis x. Furthermore, the hollow body 24 may have tubular shape along the centre axis x, especially a tapering shape along the centre axis x towards the second end 53. In the embodiments disclosed, a main part of the hollow body 24 is substantially conical. The hollow body 24 is defined by a wall 50
20 enclosing a cavity of the body 24. The hollow body 24 has a first end 52, forming an upper end during normal use of the hollow body 24, and a second end 53, forming a lower end during normal use of the hollow body 24. The hollow body 24 is provided with a plurality of slit-shaped openings 55 extending through the wall 50.

25 The second end 53 is in some of the embodiments closed. The first end 52 is open and adapted for receiving the liquid to be introduced into the cartridge 9. The liquid leaves the cavity of the hollow body 24 through the slit-shaped openings 55 in a flow direction b. Each
30 such slit-shaped opening 55 defines a specific, respective flow direction b, see Figs 6 and 7. The hollow body extends downwardly into the inner space 10 of the cartridge 9. At least initially, the hollow body 24 extends down to the liquid 28 and the particulate material 20, so that the liquid supplied via the hollow body 24 may
35 flow substantially horizontally into the bed of particulate material 20, or at least into the liquid 28.

Atty. Docket No. N0267-US01

In the same manner as for the filter 23, each slit-shaped opening 55 has a first extension, indicated by the line 61 in Fig 6, and a second extension, indicated by the line 62 in Figs 6 and 7. The second extension 62 is substantially perpendicular to the first extension 61.
5 Both the second extension 62 and the first extension 61 are substantially perpendicular to the flow direction b.

The second extension 62 is significantly shorter than the first extension 61. Moreover, the second extension 62 is significantly
10 shorter than the length 63 of the slit-shaped opening 55 in the flow direction b. In particular, the second extension 62 is equal to or less than 0,1 mm, preferably equal to or less than 0,08 mm. Moreover, the second extension 62 is equal to or more than 0,02 mm, preferably equal to or more than 0,04 mm. According to a preferred
15 embodiment, the second extension 62 is approximately 0,06 mm.

The hollow body 24 is made in a polymer material, for instance polycarbonate or polypropylene. The hollow body 24 may be
20 manufactured through an injection moulding process by injecting said polymer material into a mould cavity having the shape of the hollow body 24. Each slit-shaped opening 55 has an upstream end and a downstream end with respect to the respective flow direction b. As appears from Fig 7, the second extension 62 of the slit-shaped opening 55 increases in the flow direction b from a minimum
25 value at the upstream end of the slit-shaped opening 55 to a maximum value at the downstream end of the slit-shaped opening 55. Such a shape of the slit-shaped openings 55 facilitates the injection moulding process of the hollow body 24.

30 The hollow body 24 also has an engagement portion 71 at the first, upper end 52 to be engaged by an upper portion of the cartridge 9. This upper portion may be formed by an attachable lid 72. The upper portion has an aperture into which the hollow body is introduced. The engagement portion 71 includes two flanges 73 and
35 74 extending around the outer periphery of the hollow body 24 and provided successively after each other along the centre axis x. When introduced into the aperture of the upper portion, the flanges

Atty. Docket No. N0267-US01

73, 73 are arranged on a respective side of the wall of the upper portion or the lid 72 as appears from Fig 2. Alternatively, the hollow body 24 may be manufactured in one single piece with the upper portion or the lid 72.

5

The hollow body 24 may also be provided with one or several elongated flanges or ridges 76. One such flange 76 is disclosed by dotted lines in Fig 2. The flanges 76 may be arranged longitudinally along the inside wall of the hollow body 24. The flanges 76 may act as "liquid guides". The incoming liquid may then follow the inside wall of the hollow body 24 or flow along the flanges 76. Alternatively, the liquid guides may include plastic pellets.

10 In the embodiment disclosed in Fig 8, the hollow body 24 has a main wall portion 81 which has a substantially conical shape. In the proximity of the second lower end 53, the conical wall portion 81 of the hollow body 24 is provided with a plurality of slit-shaped openings 55 uniformly distributed around the hollow body 24. The first extension 61 of each slit-shaped opening 55 has a first main component extending in parallel with the centre axis x, and, due to the conical shape of the wall portion 81, a second minor component extending substantially radially outwardly from the centre axis x. The flow direction b may thus extend outwardly with a substantially right angle to the centre axis x. It is to be noted that the hollow body 24 may also have another cross-sectional shape than a circular one, for instance oval, triangular, square, rectangular or any other polygonal shape. In case of any polygonal shape, all or a selected number of the side walls so formed may be provided with slit-shaped openings 55. In particular, it may be mentioned that if the hollow body 24 has a square or rectangular cross-sectional shape only one or two of the side walls may be provided with slit-shaped openings 55.

35 In the embodiment disclosed in Fig 9, the hollow body 24 also has a main wall portion 81 which has a substantially conical shape. In addition, at the second lower end 53, the hollow body 24 has a smaller wall portion 82, which has a tip-like shape, and more

precisely a substantially conical shape. The cone angle with respect to the centre axis x is significantly greater for the smaller wall portion 82 than for the major wall portion 81. The smaller conical wall portion 82 is provided with a plurality of slit-shaped openings
5 55 uniformly distributed around the hollow body 24. The first extension 61 of each slit-shaped opening 55 has a first component extending in parallel with the centre axis x and second component extending substantially radially outwardly from the centre axis x. Thus the flow direction b will form an angle to the centre axis x. It is
10 to be noted that also in this embodiment, the hollow body and the smaller wall portion 82 may have another cross-sectional shape than a circular one, for instance oval, triangular, square, rectangular or any other polygonal shape. Also in this case the number of side walls provided with slit-shaped openings 55 may be selected in
15 accordance with circumstances.

In the embodiment disclosed in Fig 10, the hollow body 24 also has a main wall portion 81 with a substantially conical shape. In addition, at the second lower end 53, the hollow body 24 has a
20 smaller wall portion 83, which has a substantially plane shape. The wall portion 83 is positioned in such a way that the plane wall portion 83 is sloping and that a normal direction of the wall portion 83 and forms an angle of inclination to the centre axis x. In the embodiment disclosed, this angle is close to 90°. The plane wall
25 portion 83 is provided with a plurality of slit-shaped openings 55 extending in parallel to each other. The first extension 61 of each slit-shaped opening 55 has a first component extending in parallel with the centre axis x. Also in this case, the flow direction b will form an angle to the centre axis x, which is close to 90°.

30 In the embodiment disclosed in Fig 11, the hollow body 24 also has a main wall portion 81 with a substantially conical shape. In addition, at the second lower end 53, the hollow body 24 has a smaller transverse wall portion 84, which has a substantially plane
35 shape. The transverse plane wall portion 84 is positioned in such a way that a normal direction of the wall portion 84 is parallel with the centre axis x. The transverse plane wall portion 84 is provided with

Atty. Docket No. N0267-US01

a plurality of slit-shaped openings 55 extending in a radial direction with respect to the centre axis x. The layout of the slit-shaped openings 55 of the transverse wall portion 84 is similar to the layout of the slit-shaped openings 30 of the disc 29 of the filter 23.

5

By means of the hollow body 24 for the supply of liquid to the particulate material 20, the liquid will be introduced directly into the particulate material 20 or the liquid layer 28. The liquid may then be prevented from freely falling in drops down to the liquid surface.

10 The pressure waves and the currents will then be directed towards the inside wall of the cartridge 9 and dampened out before reaching the particulate material 20. The channelling effect may thus be minimised. According to the embodiments of Figs 8 to 10, the liquid may also be introduced substantially horizontally into the particulate
15 material 20 or into the liquid layer 28. Tests have shown that the functioning time before an alarm is triggered can be prolonged as much as two hours compared to when using a prior art cartridge, intended for example for 8 hours of use.

20 The present invention is not limited to the embodiments disclosed but may be varied and modified within the scope of the following claims. For example, the pattern of slits may be as shown, or may take on a more randomised pattern which may be localized near the lower end or may be spread through various positions, orderly or
25 randomised over the length of the device. Also in the embodiments disclosed the first extension 31, 61 of the filter 23 and the hollow body 24 is substantially straight. It is to be noted, however, that the first extension 31, 61 as an alternative may be curved.

30

Atty. Docket No. N0267-US01

Claims

1. A device for use in a cartridge (9) for preparing a liquid solution for a medical procedure, said device comprising a hollow
5 body (24) defined by a wall (50) enclosing a cavity of the body, the body having a first end (52) and a second end (53), and being provided with a least one slit-shaped opening (55) extending through the wall, said first end being open and adapted for receiving liquid to be introduced into the cartridge (9), which liquid
10 leaves the device through said slit-shaped opening (55) in a flow direction (b), wherein said slit-shaped opening has a first extension (61) and a second extension (62) being substantially perpendicular to the flow direction (b) and to the first extension (61), wherein the second extension (62) is significantly shorter than the first
15 extension (61).
2. A device according to claim 1, wherein said hollow body (24) has a centre axis (x) and an elongated, tubular shape along the
20 centre axis.
3. A device according to any one of claims 1 and 2, wherein said hollow body (24) is tapering along the centre axis (x) towards the
25 second end (53).
4. A device according to any one of the preceding claims, wherein said hollow body (24) at the first end (52) has engaging
30 means (73, 74) adapted for connection of the device to the cartridge (9).
5. A device according to any one of the preceding claims, wherein the second extension (62) is significantly shorter than the
35 length (63) of the slit-shaped opening (55) in the flow direction (b).
6. A device according to any one of the preceding claims, wherein the first extension (61) is substantially perpendicular to the
40 flow direction (b).

Atty. Docket No. N0267-US01

7. A device according to any one of the preceding claims,
wherein the second extension (62) is equal to or less than 0,1 mm.
8. A device according to any one of the preceding claims,
5 wherein the second extension (62) is equal to or less than 0,08 mm.
9. A device according to any one of the preceding claims,
wherein the second extension (62) is equal to or more than 0,02
mm.
- 10
10. A device according to any one of the preceding claims,
wherein the second extension (62) is equal to or more than 0,04
mm.
- 15
11. A device according to any one of the preceding claims,
wherein the second extension (62) is approximately 0,06 mm.
12. A device according to any one of the preceding claims,
wherein the device includes a plurality of slit-shaped openings (55),
20 which extend through the wall (50).
13. A device according to claim 12, wherein said slit-shaped
openings (55) are distributed around the wall (50).
- 25
14. A device according to any one of the preceding claims,
wherein said hollow body (24) has a wall portion (81-84) at least in
the proximity of the second end (53), and wherein said slit-shaped
opening (55) extend through said wall portion (81-84).
- 30
15. A device according to claim 14, wherein said wall portion (82)
has a tip-like shape.
16. A device according to claim 15, wherein said wall portion (82)
is substantially conical.
- 35
17. A device according to claim 14, wherein said wall portion (83,
84) is substantially plane.

Atty. Docket No. N0267-US01

18. A device according to claim 17, wherein a normal direction of said wall portion (83) forms an angle of inclination to the centre axis (x).
- 5 19. A device according to any one of the preceding claims, wherein the flow direction (b) forms an angle to the centre axis (x).
- 10 20. A device according to claim 18, wherein the centre axis (x) extends substantially in parallel with a normal direction of the plane wall portion (84).
- 15 21. A device according to any one of the preceding claims, wherein the slit-shaped opening (55) has an upstream end and a downstream end with respect to the flow direction (b), wherein the second extension of the slit-shaped opening increases in the flow direction (b) from a minimum value at the upstream end of the slit-shaped opening to a maximum value at the downstream end of the opening (55).
- 20 22. A cartridge for preparing a liquid solution for a medical procedure and arranged to contain a particulate material (20), wherein the cartridge (9) includes:
- 25 an inner space (10) for housing the particulate material (20);
- an inlet (21) arranged to permit the introduction of a liquid into the inner space (10);
- an outlet (22) arranged to permit the discharge of liquid from the inner space (10); and
- 30 a device comprising a hollow body (24) defined by a wall (50) enclosing a cavity of the body, the body having a first end (52) and a second end (53), and being provided with a least one slit-shaped opening (55) extending through the wall, said first end being mounted to the cartridge (9) at the inlet in such a manner that the body (24) extends into the inner space (10) and said second end is
- 35 located in the inner space of the cartridge, said first end being open and adapted for receiving said liquid to be introduced into the cartridge, which liquid leaves the device through said slit-shaped

Atty. Docket No. N0267-US01

opening (55) in a flow direction (b), wherein said slit-shaped opening has a first extension (61) and a second extension (62) being substantially perpendicular to the flow direction (b) and to the first extension (61), wherein the second extension (62) is
5 significantly shorter than the first extension (61).

23. A cartridge for preparing a liquid solution for a medical procedure and arranged to contain a particulate material, wherein the cartridge (9) includes:
10 an inner space (10) for housing the particulate material;
an inlet (21) arranged to permit the introduction of a liquid into the inner space;
an outlet (22) arranged to permit the discharge of liquid from the inner space; and
15 a device according to any one of claims 2 to 21, wherein the first end (52) is mounted to the cartridge (9) at the inlet in such a manner that the body extends into the inner space and said second end is located in the inner space.

20 24. A cartridge according to any one of claims 22 and 23, wherein the cartridge (9) includes filter (23) arranged at the outlet (22) and to permit passage of the liquid through the filter (23), but to prevent passage of the particulate material through the filter, wherein the filter permits the liquid to pass through the filter in a filter direction
25 (a).

25. A cartridge according to claim 24, wherein the filter (23) includes at least one slit-shaped opening (30), which has a first extension (31) and a second extension (32) being substantially
30 perpendicular to the filter direction (a) and to the first extension, wherein the second extension is significantly shorter than the first extension.

26. A use of a device in a cartridge (9) for preparing a liquid
35 solution for a medical procedure and arranged to contain a particulate material (20), wherein the cartridge includes:
an inner space (10) for housing the particulate material;

Atty. Docket No. N0267-US01

an inlet (21) arranged to permit the introduction of a liquid into the inner space;

an outlet (22) arranged to permit the discharge of liquid from the inner space; and

- 5 said device comprising a hollow body (24) defined by a wall (50) enclosing a cavity of the body, the body having a first end (52) and a second end (53), and being provided with a least one slit-shaped opening (55) extending through the wall, said first end being mounted to the cartridge (9) at the inlet (21) in such a manner that
10 the body extends into the inner space (10) and said second end (53) is located in the inner space of the cartridge, said first end being open and adapted for receiving said liquid to be introduced into the cartridge (9), which liquid leaves the device through said slit-shaped opening (55) in a flow direction (b), wherein said slit-shaped opening has a first extension (61) and a second extension (62) being substantially perpendicular to the flow direction (b) and to the first extension, wherein the second extension (62) is
15 significantly shorter than the first extension (61),
the use including the step of supplying said liquid to the cartridge
20 (9) via the inlet (21) in such a way that the liquid passes through the particulate material (20) and thereby dissolves at least a part of the particulate material to form a liquid solution.

25 27. A use according to claim 26, wherein the liquid is a dialysis liquid.

28. A use according to any one of claims 26 and 27, wherein the particulate material includes bicarbonate and/or sodium chloride.

30 30. A use according to any one of claims 26 to 28, wherein the device includes the features of any one of claims 2 to 21.

31. A system for preparing a liquid solution for a medical procedure, the system including:

35 a cartridge (9) containing a particulate material in an inner space thereof and including an inlet and an outlet;

Atty. Docket No. N0267-US01

- a first liquid (3) conduit having a first end (4) communicating with a source (1) of liquid to withdraw the liquid into the first liquid conduit and a second end;
- 5 a second liquid conduit (6) having a first end (7) communicating with a source (1) of liquid and a second end (8) communicating with the inlet of the cartridge (9) for introducing the liquid into the inner space (10) to produce a concentrate liquid solution containing at least a part of the particulate material dissolved in the liquid;
- 10 a third liquid conduit (11) communicating with the outlet of the cartridge and with a mixing point (13) in the first liquid conduit (3) intermediate said first and second ends (4, 5) for conducting said concentrate liquid solution from the cartridge (9) into said first liquid conduit to be mixed with the liquid being conducted through the first liquid conduit to thereby produce said liquid solution in the first
- 15 liquid conduit for delivery to said second end of the first liquid conduit; and
- a device comprising a hollow body (24) defined by a wall (50) enclosing a cavity of the body, the body having a first end (52) and a second end (53), and being provided with a least one slit-shaped
- 20 opening (55) extending through the wall, said first end being mounted to the cartridge (9) at the inlet in such a manner that the body extends into the inner space (10) and said second end (53) is located in the inner space of the cartridge, said first end being open and adapted for receiving said liquid to be introduced into the cartridge, which liquid leaves the device through said slit-shaped
- 25 opening (55) in a flow direction (b), wherein said slit-shaped opening has a first extension (61) and a second extension (62) being substantially perpendicular to the flow direction (b) and to the first extension (61), wherein the second extension (62) is
- 30 significantly shorter than the first extension (61).

32. A system according to claim 31, wherein the device includes the features of any one of claims 2 to 21.

- 35 33. A system according to any one of claims 31 and 32, wherein the cartridge (9) includes filter (23) arranged at the outlet (22) and to permit passage of the liquid through the filter (23), but to prevent

Atty. Docket No. N0267-US01

passage of the particulate material through the filter, wherein the filter permits the liquid to pass through the filter in a filter direction (a).

- 5 34. A system according to claim 33, wherein the filter includes at least one slit-shaped opening (30), which has a first extension (31) and a second extension (32) being substantially perpendicular to the filter direction (a) and to the first extension, wherein the second (32) extension is significantly shorter than the first extension (31).
- 10
35. A system according to any one of claims 31 and 34, wherein the liquid is a dialysis liquid.
- 15 36. A system according to any one of claims 31 to 35, wherein the particulate material includes bicarbonate and/or sodium chloride.

Atty. Docket No. N0267-US01

Abstract

5 The present invention relates to a device for use in a cartridge (9),
a cartridge, a use of a device in a cartridge and a system for
preparing a liquid solution for a medical procedure. The device
comprises a hollow body (24) defined by a wall (50) enclosing a
cavity space of the body. The body (24) has a first end (52) and a
second end (53), and is provided with a least one slit-shaped
opening (55) extending through the wall. The first end is open and
10 adapted for receiving liquid to be introduced into the cartridge. The
liquid leaves the device through the slit-shaped opening in a flow
direction. The slit-shaped opening has a first extension and a
second extension substantially perpendicular to the flow direction
and to the first extension. The second extension is significantly
15 shorter than the first extension.

(Fig 2)

Fig 1

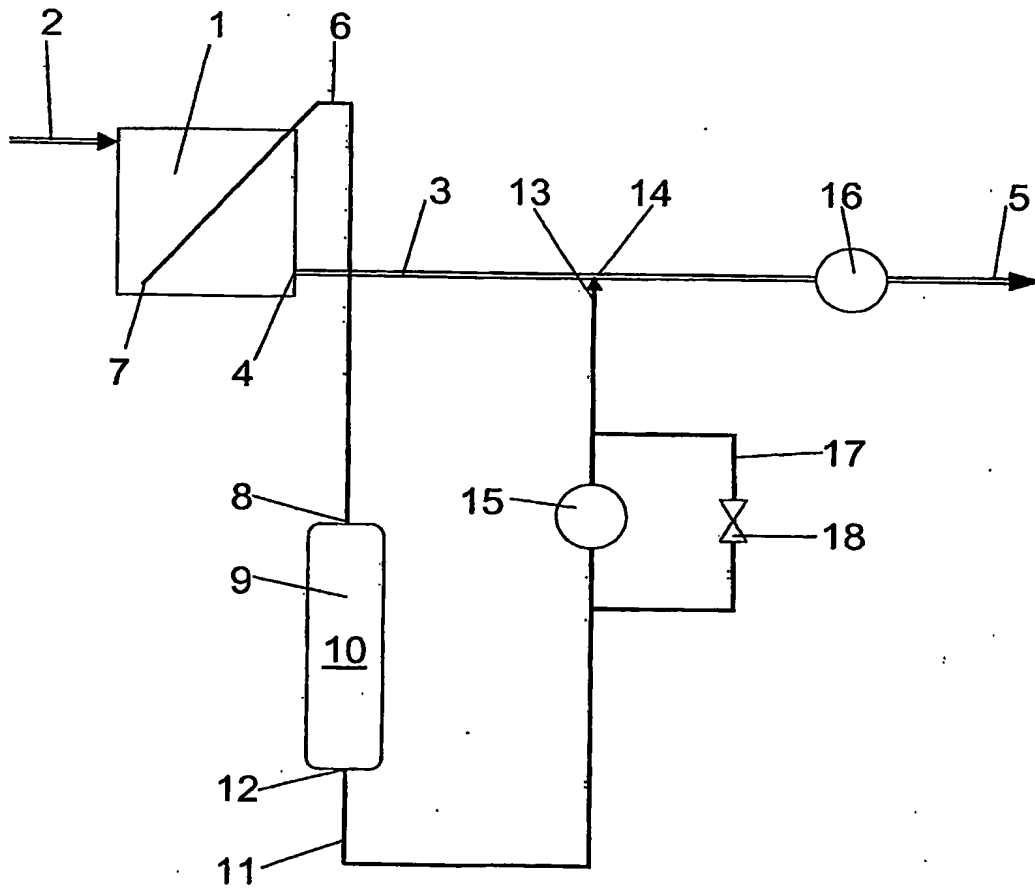
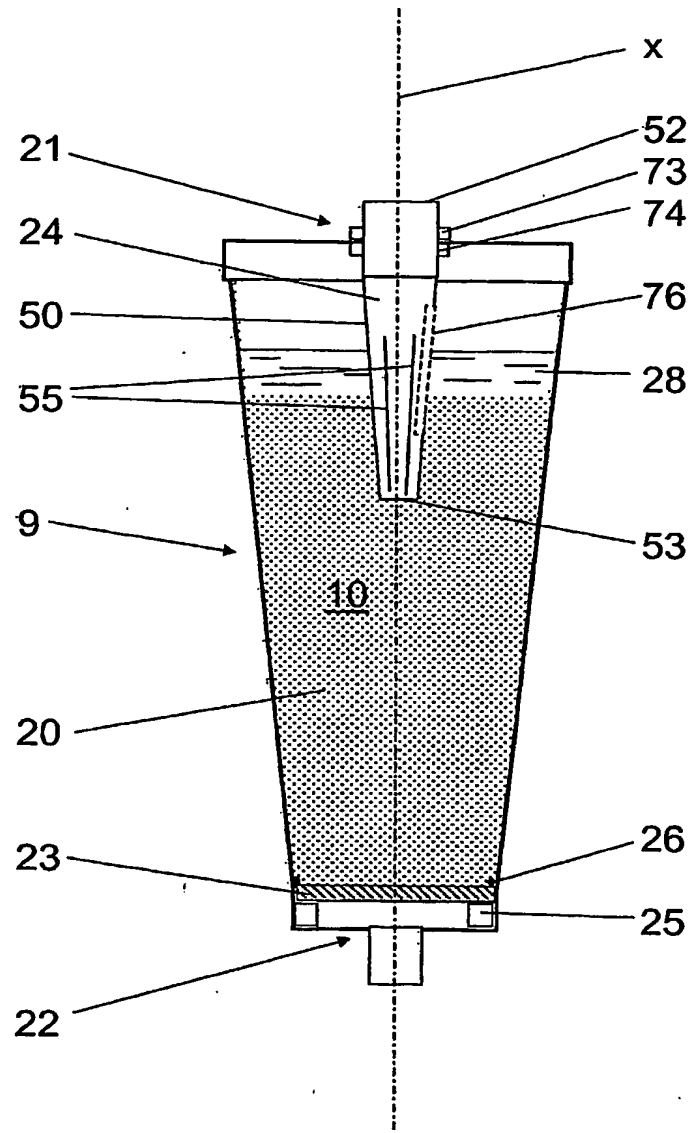


Fig 2



N0267-4501

4/8

Fig 6

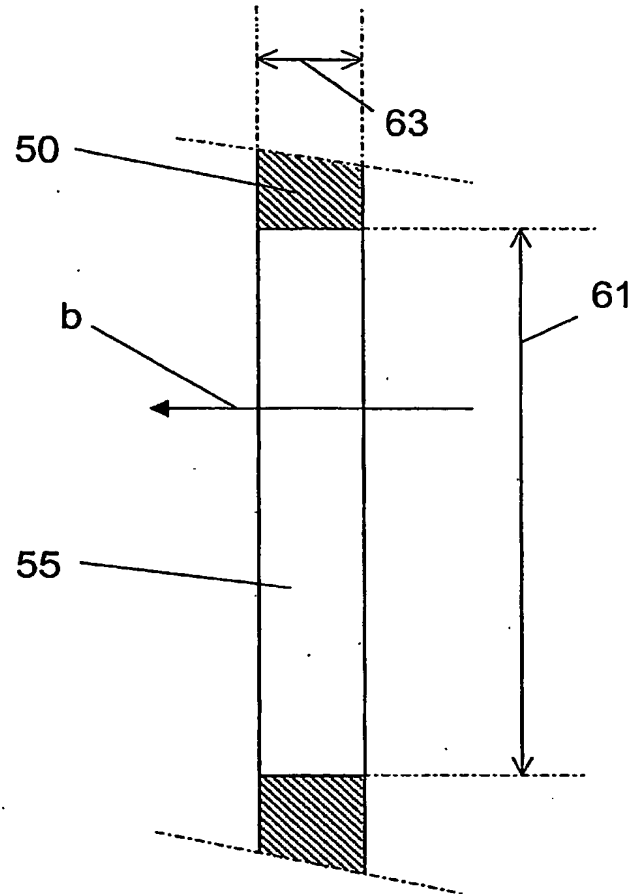
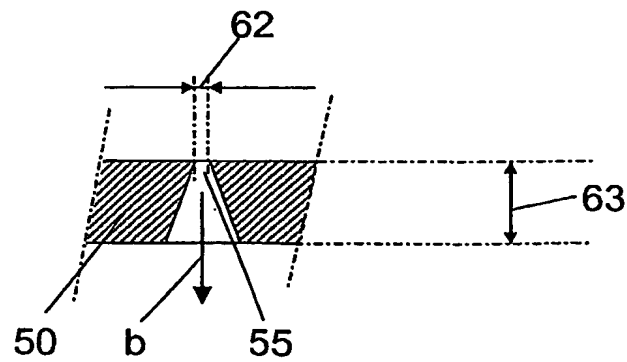


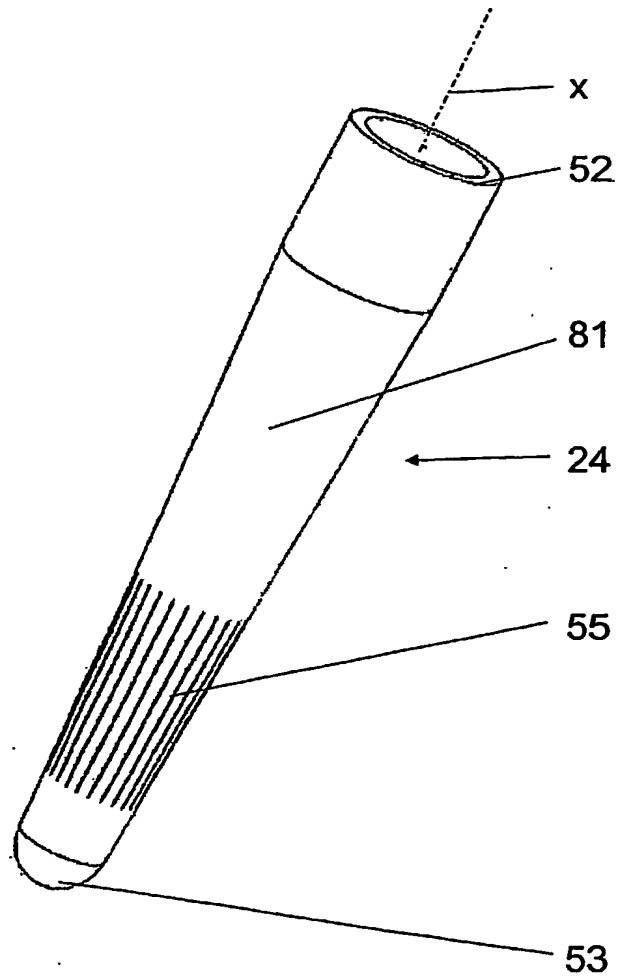
Fig 7



N0267-1501

5/8

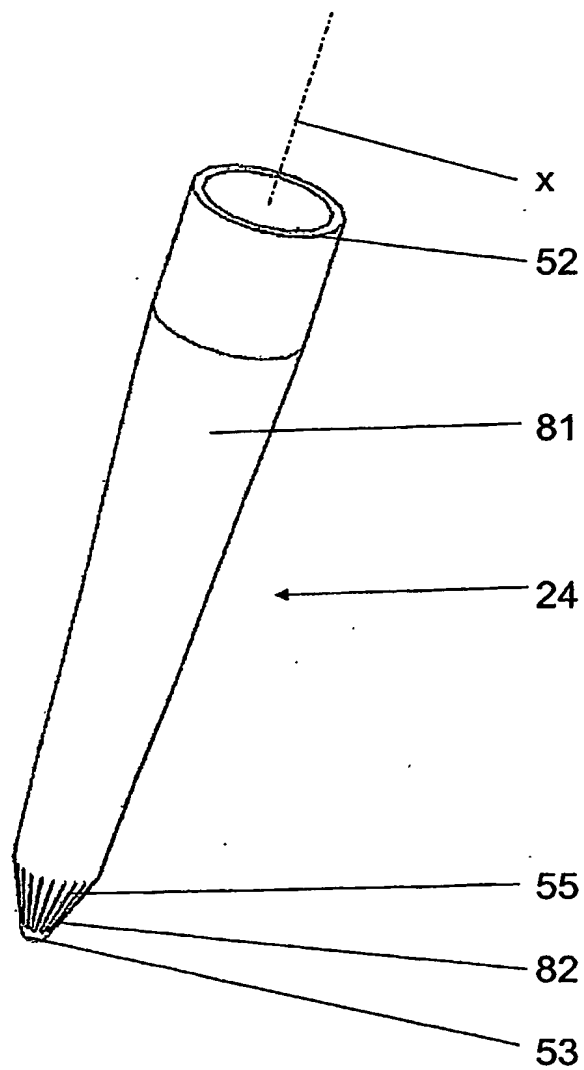
Fig 8



N0267-0501

6/8

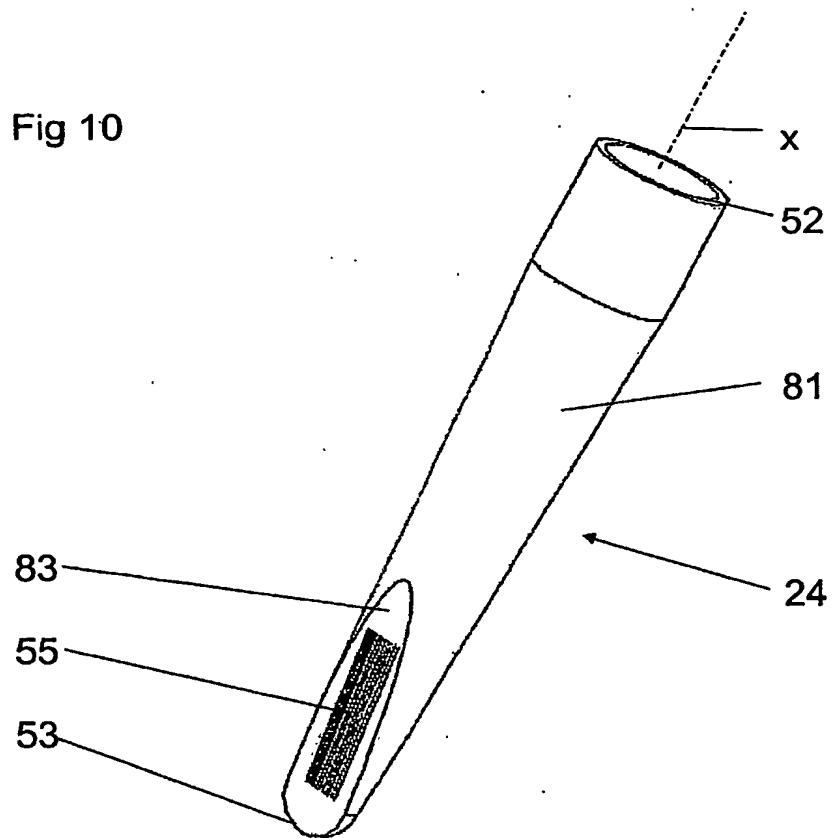
Fig 9



N0267-4501

7/8

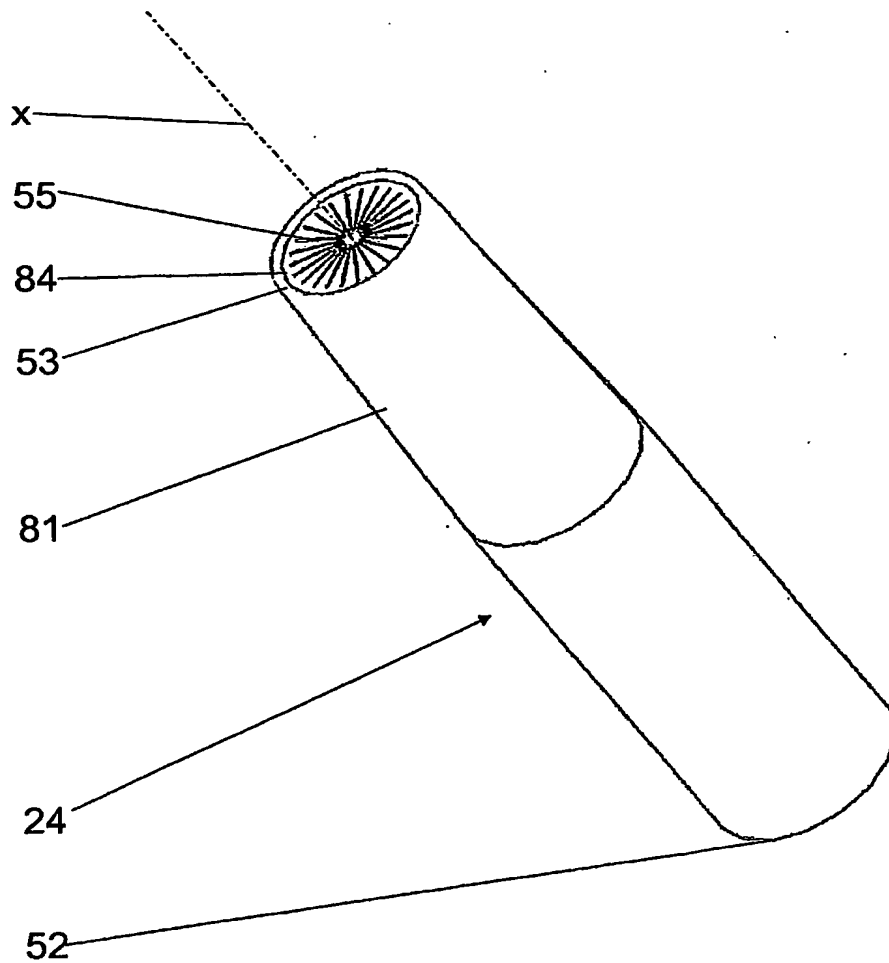
Fig 10



N0267-4501

8/8

Fig 11



**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☒ BLACK BORDERS
- ☒ IMAGE CUT OFF AT TOP, BOTTOM OR SIDES
- ☐ FADED TEXT OR DRAWING
- ☐ BLURRED OR ILLEGIBLE TEXT OR DRAWING
- ☐ SKEWED/SLANTED IMAGES
- ☐ COLOR OR BLACK AND WHITE PHOTOGRAPHS
- ☐ GRAY SCALE DOCUMENTS
- ☐ LINES OR MARKS ON ORIGINAL DOCUMENT
- ☒ REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY
- ☐ OTHER: _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.